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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,287

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Hideaki Yamaoka

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EXAMINER

GEHMAN, BRYON P

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,287	Applicant(s) YAMAOKA, HIDEAKI	
	Examiner Bryon P. Gehman	Art Unit 3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,13,16,17,19-22 and 29-37 is/are pending in the application.
- 4a) Of the above claim(s) 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,11,13,16,17,19-22 and 29-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Newly submitted claims 35 and 36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 10-11, 13, 16-17, 19-22 and 29-35 drawn to a biosensor disposed in a container, classified in class 206, subclass 459.5.
- II. Claims 36 and 37, drawn to a method of inspecting biosensors, classified in class 356, subclass 600.

The inventions are independent or distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed does not require the biosensors be checked during the containing step, but allows their inspection at any time prior to and after disposition within the container.

Since applicant has received actions on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36 and 37 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10-11, 13, 16-17, 19-22 and 29-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention in the manner now identified. As originally claimed and disclosed, the particular composition of the biosensor made no difference, as disclosed, for the purpose of inspection of the biosensor in the claimed biosensor–container combination. At page 7, lines 3-4 of the original specification, the particular biosensors subsequently disclosed are indicated as an example only, and there is no disclosed criticality disclosed as to the particular biosensor structure claimed being critical to the claimed combination of a container with biosensors contained therein. Accordingly, there is no original disclosure to support any relationship of criticality of a particular biosensor contained within the container to the combination as claimed. Applicant's reliance of the biosensor structure to provide some nexus of an inventive nature is lacking from the original disclosure. The biosensor per se was disclosed as an example of a conventional biosensor, and was indicated to be of unpatentable significance by itself (never claimed individually as an inventive biosensor per se), nor was there any disclosure of a particular relationship with the claimed container to the particular structure of the biosensor so as to render their combination of patentable significance.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 10, 13, 16-17, 19-22 and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001141686 in view of Stewart et al. (4,589,547). JP 2001141686 discloses a sensor-container combination comprising a container including a container body (3), and a plurality of sensors stored in the container. Stewart et al. disclose providing a container (30) with a transparent container body to allow viewing of the content of the container, and a non-transparent lid (33ba). To modify the container of JP 2001141686 employing the transparent container body and non-transparent lid teaching of Stewart et al. would have been obvious in order to allow selective visual ascertaining of the content of the sensor container, as suggested by Stewart et al.. The provision of portion of transparency as opposed to entire transparency is considered an obvious matter of choice and degree, the differences provided not being new or unobvious to one of ordinary skill in the art. "A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int 'l v. Teleflex Inc.*, 127 S. Ct. 1731, 82 USPQ2d at 1396. The remainder of the claimed subject matter pertains to a particular biosensor disclosed by the applicant beginning at page 7 of the specification to be by way of example only,

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and accordingly identified as by applicant as conventional and not of any particular relation to the container structure. Applicant, at the time the invention was made, indicated that the biosensor per se was not of an inventive nature. Accordingly, the container-biosensor combination has been merely limited to a very particular biosensor, but one which applicant has himself identified and disclosed as being by way of example only, and not itself inventive in its combination with the container. Furthermore, the particular biosensor as claimed is not seen, in the claimed container-biosensor combination, to distinguish any new or unobvious difference from the container and any other conventional biosensor in combination. Accordingly, since there is no disclosed nexus between the claimed container and a particular biosensor structure to render the container-biosensor combination new and unobvious, the extreme limiting of the biosensor structure fails to distinguish any new or unexpected result from the mere particular definition of a biosensor.

In the dependent claims, the further limitations to a particular biosensor fail to render the claimed container-biosensor combination of any new or unobvious arrangement.

6. Claims 10, 13, 16, 19-22, 30-31 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001141686 in view of Stewart et al. (4,589,547), the article to Morris, Feldman et al. (6,461,496), and Karinka et al. (7,501,053). JP 2001141686 discloses a sensor-container combination comprising a container including a container body (3), and a plurality of sensors stored in the container. Stewart et al.

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disclose providing a container (30) with a transparent container body to allow viewing of the content of the container, and a non-transparent lid (33ba). To modify the container of JP 2001141686 employing the transparent container body and non-transparent lid teaching of Stewart et al. would have been obvious in order to allow selective visual ascertaining of the content of the sensor container, as suggested by Stewart et al.. The provision of portion of transparency as opposed to entire transparency is considered an obvious matter of choice and degree, the differences provided not being new or unobvious to one of ordinary skill in the art. Morris discloses a sensor including an oxidation-reduction enzyme, a mediator that mediates transfer of electrons caused by oxidation or reduction, a sensor previously known to those of ordinary skill in the field of biosensors. To employ sensors having the conventional properties described above in the modified container combination would merely be the incorporation of a particular biosensor in the general container. "A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int 'l v. Teleflex Inc.*, 127 S. Ct. 1731, 82 USPQ2d at 1396. **Applicant has originally disclosed the particular biosensor per se to not be of an inventive concept, and by way of an example only.** Feldman et al. further discloses sensors that are composed of materials resistant to ultraviolet light, therefor having inherent lightfastness. The base sensors do not expressly define ammonia serving as nitrogen associated with a ligand in a biosensor. To any degree the generic nitrogen-containing ligand of Feldman et al. would not obviously include ammonia as nitrogen, Karinka et al. further discloses a biosensor united with a ammonia –containing ligand (see column

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5, line 55 through column 6, line 52). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a sensor of the claimed sensor-container combination with an ammonia-containing ligand as claimed, as such a modification would predictably serve the purpose intended therefor as disclosed by Karinka et al. to provide an advantageous sensor. "A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int 'l v. Teleflex Inc.*, 127 S. Ct. 1731, 82 USPQ2d at 1396.

To modify the claimed container of JP 2001141686 employing a particular sensor therein would have been obvious, the choice alterations to the biosensor such as per one combining the general teachings of Morris, Feldman et al. and Karinka et al. being an obvious substitution to one of ordinary skill in the art in order to derive the advantages of a particular sensor per se in the claimed sensor-container combination. Motivation for Morris is KSR substitution of one known reagent for another with expected results (Feldman discloses that a variety of reagents could be used). One with ordinary skill in the art at the time of the invention would have been able to select the appropriate reagent for the analyte of interest from known reagent compositions for electrochemical test strips. Also, optimization is a motivation as the Morris abstract discloses linear and accurate sensor response over the range of 2-30 mM and minimizing interference from interferants (see penultimate paragraph). Although Morris does not mention whether ruthenium hexamine is lightfast, applicant has disclosed this as an inherent property.

If the biosensor itself were inventive, it would have been claimed individually. In any case, its combination in the claimed container combination provides no new or unexpected result. The invention is the combination of a particular container with a biosensor. The further particularity of the biosensor does not render the combination of a container and the biosensor inventive as a combination. Applicant has originally disclosed the biosensor composition to be arbitrary.

As to claims 13 and 30, Feldman et al. further discloses sensors that are composed of materials resistant to ultraviolet light, therefor having inherent lightfastness.

As to claims 16 and 31, Karinka et al., Feldman et al. and Morris each recognize electrode sensors as detection means is conventional biosensor structure.

As to claims 19 and 33, Stewart et al. discloses a circular shape for the container. To modify the shape of any container to the cross-sectional shape of its intended contents as claimed would entail a mere change in shape of the container and yield only predictable results. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1740, 82 USPQ2d 1396 (2007). A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

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As to claims 20 and 34, to provide the container body and lid of a conventional hinged arrangement would have been obvious in order to maintain the container body and lid in conjunction for ease of reclosing of the container body, as is conventional knowledge to one of ordinary skill in the art.

As to claims 21 and 35, to provide the container of particular color is a design consideration only, and does not distinguish any new or unexpected utility by its selection in and of itself.

7. Claims 11 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the art as applied to claim 10 above, and further in view of either one of Yamamoto et al. (4,889,229) and Swain (3,139,976). The previous combination does not provide for a scale indicating the amount of contents in the container. Yamamoto et al. and Swain each disclose providing a container (11; 11; respectively) that is transparent and provided with a scale (15; 17 and 18) to allow viewing and determining the remaining content of the container. To modify the container of the previous combinations employing the scaled transparent container teaching of either one of Yamamoto et al. and Swain would have been obvious in order to ascertain the remaining content of the sensor container, as suggested in general for contents by either one of Yamamoto et al. and Swain.

8. Claims 17 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over the art of paragraph 6 above as applied to claims 10 and 22 above, and further in

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view of either one of Blackburn et al. (6,761,816) and Cozzette et al. (5,200,051). To employ colorimetric sensors as a detection means in a sensor is disclosed by each of Blackburn et al. and Cozzette et al..

9. Applicant's arguments filed November 20, 2009 have been fully considered but they are not persuasive. Upon consultation with the people of the USPTO familiar with biosensors, it has been determined that the biosensor, while particular, does not appear to be inventive. Furthermore, applicant's original disclosure is that the biosensor per se disclosed was not an invention, but merely an example of a workable biosensor in the combination. It appears now that applicant is trying to base the claimed container-biosensor combination is "inventive" because of the particular biosensor indicated by applicant to not be of an inventive nature has now accrued some sort of new and unexpected inventiveness! Rather, it appears merely to be a particular, but certainly not inventive, example of a biosensor that can be employed in the claimed combination as disclosed, but fails to accord the combination any new or unexpected result therefrom, but merely a "particularity". If applicant thought the biosensor per se was itself inventive, such would have been so claimed, but applicant did not disclose it to be so. Since applicant does not find the biosensor per se to be of an inventive construction, neither does the examiner.

Applicant is not claiming a biosensor per se as an invention, and by disclosure indicates such is not. Applicant discloses a container capable of holding a biosensor with particular container structure, the disclosure not indicating the relationship of the

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container and any particular biosensor being inventive in any way because of the biosensor.

10. This action is made non-final in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryon P. Gehman whose telephone number is (571) 272-4555. The examiner can normally be reached on Tuesday through Thursday from 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bryon P. Gehman/

Bryon P. Gehman

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Primary Examiner, Art Unit 3728

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